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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,382	03/20/2001	Ashutosh Chilkoti	4176-101	1286

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,382

Applicant(s)

CHILKOTI, ASHUTOSH

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-19,21-28,31,32,62-72,74-76 and 78-85 is/are pending in the application.
- 4a) Of the above claim(s) 62-65 and 83-85 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-19,27,28,32,71,72,75 and 82 is/are allowed.
- 6) ☒ Claim(s) 1, 3-10,21-26,31,66-70,74, 76 and 79-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 23 June 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7/2/2001 6) ☐ Other: _____

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The Amendment and the Affidavit under 37 CFR § 1.132 of Dr. Susan Dagher filed March 1, 2004 are acknowledged. Amendments to the claims have been entered as requested. Claims 1, 8, 27, 31, 71, 72, 74-75 and 81-82 are amended; claims 2, 11, 20, 29-30, 33-61, 73 and 77 are cancelled. Claims 1, 3-10, 12-19, 21-28, 31-32, 62-72, 74-76 and 78-85 are pending. Claims 1, 3-10, 12-19, 21-28, 31-32, 66-72, 74-76 and 78-82 are the subject of this Office Action. Claims 62-65 and 83-85 are withdrawn from consideration as directed to non-elected invention.

DETAILED ACTION

1. Rejections

1.1. 35 USC section 112, second paragraph

Rejection of claims 1, dependent claims 3-10, 12-19, 21-26, 66-70, and claim 8, 71, 74- 75 made in the Office Action of October 1, 2003 is withdrawn because the claims have been amended.

Claim 78 is rejected as lacking antecedent bases. The claim recites the limitation "the phrase transition temperature". There is insufficient antecedent basis for this limitation in the claim.

Claim 31 is rejected as being a duplicate of claim 12.

Claim 74 is rejected as being a duplicate of claim 72.

1.2. 35 USC section 112, first paragraph

1.2.1. Lack of written description

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Claims 1, 3-10, 21-26, 66-70, 79, 80, and 81 are still rejected. The claims are directed to a fusion protein exhibiting a phase transition, comprising one or more peptides or proteins (a), one or more proteins exhibiting inverse phase transition (b) and a spacer (c) wherein the fusion protein retains the inverse phase transition behavior of the phase transition protein and wherein the phase transition protein has a molecular weight of at least 9,000 Da. Thus, the claims are directed to large and variable genus of fusion proteins exhibiting a phase transition.

Regarding parts a) and c), in the light of providing new data by the Affidavit, as well as because the Applicants arguments were found persuasive, examiner concludes that the rejection for lack of written description of these parts of the fusion protein is withdrawn. However, claims 1, 3-10, 21-26, 66-70, 79, 80 and 81 are still rejected for lack of written description of structure of part b), i.e. proteins exhibiting inverse transition and transferring the inverse transition property to the fusion protein.

Traversing this rejection the Applicants write, "It has been well established that **what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail, and is preferably omitted, by a patent specification**", page 19 of Remarks, line 13 and further "the structures of various phase transition proteins exhibiting inverse phase transition were well known at the time the present application was filed...the instant specification on page 13, lines 17-20, and page 14, page 13-14", the same page, line 18.

The Applicants' argument has been fully considered, but is found not persuasive, because Applicants disclosed only the fusion proteins containing multiple repeats of the pentapeptide Val-Pro-Gly-X-Gly, wherein said repeats have as a whole molecular weight of at least 9,000 Daltons and the whole fusion proteins have the property of phase transition proteins. Therefore it is not that pentapeptides or phase transition proteins are not known to those skilled in the art, but the fusion protein containing repeats of the transition proteins or peptides are not.

Rejection of claim 9, 66-72, and 74-75 because neither the claim nor the specification describe the phase transition of the claimed fusion protein wherein the phase transition is mediated by changing pH, addition of solutes and/or solvents, side chain ionization, chemical modification, and changing pressure is withdrawn; Applicants' arguments are found persuasive.

2. Conclusion

Claims 12-19, 27-28, 32, 71-72, 75 and 82 are allowed. The following is the examiner's reason for indicating the allowable subject matter.

Applicants disclose that fusion proteins comprising a protein of interest, a linker, and repetitions of pentapeptide Val-Pro-Gly-X-Gly having molecular weight higher than 9,000 Da are phase transition proteins that can be used for purification of the protein of interest.

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The closest prior art is the article by McPherson et al. (Production and Purification of a Recombinant Elastomeric Polypeptide, G-(VPGVG)₁₉-VPGV, from *Escherichia coli*, Biotechnol. Prog. (1992), 8, 347-352, enclosed in Information Disclosure Statement). McPherson et al. teach a fusion protein consisting of glutathione S-transferase joined through glycine spacer to the multiplication of pentapeptide (VPGVG), which is (VPGVG)₁₉ – VPGV. The glycine spacer creates a protease recognition site for protease factor Xa. Thus, McPherson's transition protein is of molecular weight of 8,200 Da. In addition, the authors do not discuss or suggest that the glutathione S-transferase-G-(VPGVG)₁₉-VPGV fusion protein retains the inverse phase transition behavior of the elastomeric compound consisting of more than 19 repeats of many repetitions of (VPGVG), as recited in the allowed claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (571) 272-0944 and the right fax number is (571) 273-0944. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. EST.


If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

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Patent Examiner


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1600